

SEP 1 8 2001

K012413

ADMINISTRATIVE INFORMATION

Manufacturer Name:

MacroPore, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:

Kenneth K. Kleinhenz
Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994**DEVICE NAME**

Classification Name:

Plate, Bone

Trade/Proprietary Name:

MacroPore FX, PS, NS, LP

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 872.4760 - Bone Plates are intended to stabilize fractured bone structures in the oral cavity and are classified as Class II. Bone Plates have been assigned Product Code JEY.

INTENDED USE

A. General Indications: Trauma procedures of the midface or craniofacial skeleton.

Specific Indications:

- 1). Comminuted fractures of the naso-ethmoidal infraorbital areas.
- 2). Comminuted fractures of the frontal sinus wall.
- 3). Pediatric midface or craniofacial trauma
- 4). Lefort (I, II, III) fractures.
- 5). Orbital floor fractures.
- 6). Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones.
- 7). Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones.

B. General Indications: Reconstructive procedures of the midface or craniofacial skeleton..

Specific Indications:

- 1). Infant craniofacial surgery (i.e., craniosynostosis, congenital malformations, trauma, etc.).
- 2). Lefort (I, II, III) osteotomies.
- 3). Tumor reconstruction in midface or craniofacial procedures.
- 4). Bone graft procedures in the midface or craniofacial skeleton.
- 5). Pediatric reconstructive procedures.
- 6). Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones.
- 7). Craniotomy flap fixation.

DEVICE DESCRIPTION

Design Characteristics

MacroPore FX, PS, NS, LP is a resorbable bone fixation system composed of various sized porous sheets, non-porous sheets, and associated fixation tacks and screws manufactured from poly lactic acid. The MacroPore FX, PS, NS, LP are composed of MacroPore FX, PS, NS, LP Protective Sheets and MacroPore FX and LP Screws and Tacks. MacroPore Protective Sheets can be cut with scissors to the desired shape and size. The MacroPore Power Pen can also be used to cut or shape the MacroPore Plates and Protective Sheets to the desired shape or size.

The MacroPore Plate and Protective Sheets are fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation. The MacroPore FX, PS, NS, LP bone fixation system includes a selection of resorbable screws, tacks, and associated manual instruments. Tacks range in size from 1.5mm to 2.0mm in outer diameter. Screws range in size from 2.0mm to 2.7mm in outer diameter. The MacroPore Plates and Protective Sheets come in various sizes ranging from 0.5mm to 2.0mm in thickness according to the region to be treated. The MacroPore Protective Sheets range in size from as small as 20mm x 20mm to as large as 120mm x 120mm. The MacroPore Protective Sheet is provided with and without macroporous holes. The macroporous holes range in size from 500 microns to 3,000 microns in diameter. All configurations are to be within a mass of 18 grams of polymer.

Various manual instruments (PowerTack Driver, StarBurst Screw drivers, Tack Pusher, taps, drill bit, etc.) are used in conjunction with the MacroPore FX, PS, NS, LP bone fixation system to assist in the installation process.

Material Composition

The MacroPore FX, PS, NS, LP are fabricated from polylactic acid (PLA).

In Vitro Testing

Mechanical testing of the MacroPore FX, PS, NS, LP System demonstrates that the device is substantially equivalent to the predicate. Test results indicate that the mechanical properties of the MacroPore FX, PS, NS, LP are substantially equivalent to the mechanical properties of the predicate devices: MacroPore PX Pediatric System and MacroPore Protego System (plates, mesh, tacks, and screws) under indication for use conditions.

EQUIVALENCE TO MARKETED PRODUCT

The MacroPore FX, PS, NS, LP shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: MacroPore PX Pediatric System and the MacroPore Protective Sheet (Protego System) Class II medical devices that were cleared for marketing in the United States under K002207, K972913 respectively.

Indications For Use

The MacroPore FX, PS, NS, LP and the predicate devices share identical indications for use with the MacroPore PX Pediatric System predicate. Additionally, the MacroPore FX, PS, NS, LP devices have substantially equivalent indications for use with the MacroPore Protego System as they are both indicated for the trauma and reconstructive procedures in the midface and craniofacial skeleton.

Design and Materials

Both the MacroPore FX, PS, NS, LP and the predicate devices are manufactured from bioabsorbable materials under substantially equivalent conditions. The physical designs of MacroPore FX, PS, NS, LP and the predicate devices are substantially equivalent, consisting of plates, screws, tacks, and protective sheets. The mechanical characteristics of the MacroPore FX, PS, NS, LP and the predicate devices are substantially equivalent to the predicate device under indications for use conditions. The material used in the MacroPore FX, PS, NS, LP is also substantially equivalent to the predicate devices as they are resorbable polylactide and polyglycolide polymers. In addition to physical characteristics, both the predicate device and the MacroPore FX, PS, NS, LP can be cut and molded to specific shapes and sizes by the end user.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth K. Kleinheinz
Director of Regulatory Affairs
MacroPore, Incorporated
6740 Top Gun Street
San Diego, California 92121

Re: K012413
Trade/Device Name: MacroPore FX, PS, NS, LP
Regulation Number: 872.4760
Regulation Name: Plate Bone
Regulatory Class: II
Product Code: JEY
Dated: July 27, 2001
Received: July 30, 2001

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

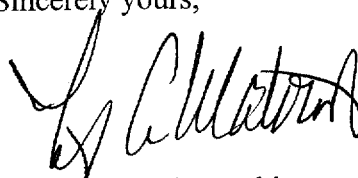
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", written over a horizontal line.

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012413

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- 7). Craniotomy flap fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

Susan P. [Signature] OR

Over-The-Counter Use ☐

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K012413